IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of.:		§		
		§		
	Michal AMIT et al	§		
		§		
Serial No.:	10/581,455	§		
		§		
Filed:	June 1, 2006	§	Group Art Unit:	1632
		§		
For:	METHODS OF GENERATING STEM CELLS AND EMBRYONIC BODIES CARRYING DISEASE-CAUSING MUTATIONS AND METHODS OF USING SAME FOR STUDYING GENETIC DISORDERS	§		
		§	Attorney Docket:	**32059**
		§		
Examiner:	TON, Thaian N	§		

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 CFR 1.132

I, Michal Amit, am presently employed as a researcher at the Technion Institute of Technology, Haifa Israel, Faculty of Medicine & Rambam Medical Center, Stem Cell Center, where I am a Senior Scientist. I received my Ph.D. degree from the Technion Institute of Technology, Israel, in Medical Sciences.

My research focuses on derivation and culturing of human embryonic stem cells. I have published 21 scientific articles in highly regarded journals and 17 reviews and scientific book chapters, and have presented my achievements at many international scientific conferences.

I am a member of the international society for stem cell research (ISSCR) and Israel Stem Cells Society (ISCS), and was awarded several research prizes including the Gutwirth Family Scholarship for Excellence, Technion, Israel Institute of Technology, 2002.

In re Application of: Michal Amit et al.
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Office Action Mailing Date: March 2, 2009

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I am a co-inventor of the subject matter claimed in the above-referenced U.S. patent application.

I have read the Office Action dated March 2, 2009, with respect to the above-identified application.

In the Office Action the Examiner rejected claims 52, 55, 56, 58-60, 74, 75, 78-80 and 82 under 35 U.S.C. 103(a) as being unpatentable over Ratcliff (Transgenic Res. 1:177-181, 1992) when taken with Thomson et al., (Science, 282:1145-1147, 1998) and US Pat. No. 7,390,659, in further view of Elsea et al., (ILAR Journal, 43:66-79, 2002); claims 83-84 under 35 U.S.C. 103(a) as being unpatentable over Ratcliff, Thomson, Elsea and PGPub US 2005/0054092; and claims 57 and 81 under 35 U.S.C. 103(a) as being unpatentable over Ratcliff, Thomson, Elsea and US Pat. No. 5,972,955.

Being an expert in the field of human embryonic stem cells, I hereby state that one of ordinary skill in the art would not have been motivated to use the teachings of Ratcliff with respect to homologous recombination in mouse ESCs in order to generate human ESC lines harboring genetic mutations, since protocols established for mouse ESCs cannot be used without major modifications on human ESCs. Thus, while mouse ESCs can be easily targeted for homologous recombination by electroporation, it has been found that human ESCs do not survive the electroporation process well (See Eiges R., et al., 2001, Page 515, left column, lines 2-3; attached herewith). In addition, while mouse ESC lines can be easily generated from a single mouse embryonic stem cell, human ESCs are not efficiently cloned (to generate a line) from a single cell (see Table 1 in Page 273 of Amit et al., 2000, attached herewith). Altogether, the major intrinsic differences between mouse and human ESCs are such that make the screening procedure of human single cells that undergo homologous recombination tedious and inefficient, let alone the generation of human ESC lines from such single cells.

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I hereby declare that all the statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and the such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: June 1, 2009.

Michal Amit

Dr. Michal Amit

Enclosed:

Michal Amit's CV and list of Publications

Eiges R., et al., 2001, Current Biology, 11:514-518;

Amit et al., 2000, Developmental Biology, 227:271-278;